

**AMENDMENT TO H.R. 6**  
**OFFERED BY MR. BUTTERFIELD OF NORTH**  
**CAROLINA**

(Page and line numbers refer to UPTON\_005)

Page 168, after line 23, add the following new section:

**1 SEC. 2153. LIMITATION ON PRIORITY REVIEW VOUCHERS**  
**2 FOR TROPICAL DISEASE PRODUCTS.**

**3** Subparagraph (A) of section 524(a)(4) of the Federal  
**4** Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(4)) is  
**5** amended—

**6** (1) in clause (i), by striking “and” at the end;

**7** (2) in clause (ii), by inserting “and” at the end;

**8** and

**9** (3) by adding at the end the following:

**10** “(iii) contains an assurance (satisfac-  
**11** tory to the Secretary) that the drug for  
**12** which the application is submitted has not  
**13** been approved for commercial marketing  
**14** for any tropical disease indication by a  
**15** government authority outside of the United

1 States for more than 36 months before the  
2 application is submitted;”.

